

**315.036 Permit to be acquired by manufacturer or wholesaler -- Exceptions -- Fee -
- Records required -- Report.**

- (1) Except as provided in subsection (4) of this section, each manufacturer or wholesaler of drugs shall be required to register with and obtain a permit from the board. Such permit shall be issued in accordance with policy and procedure prescribed by regulations of the board. Each application shall be accompanied by a reasonable permit fee to be set by administrative regulation of the board, not to exceed two hundred fifty dollars (\$250) annually or increase more than twenty-five dollars (\$25) per year.
- (2) Manufacturers and wholesalers shall be required to maintain accurate records of all drugs manufactured, received and sold, as established by administrative regulation of the board. Such records shall be made available to agents of the board for inspection at reasonable times. The board may require by regulation that manufacturers and wholesalers periodically report to the board all drugs manufactured, received, and sold.
- (3) Failure to report to the board or willful submission of inaccurate information shall be grounds for disciplinary action under the provisions of KRS 315.131.
- (4) The provisions of subsection (1) of this section do not apply to a pharmacist who, in the normal course of professional practice:
 - (a) Compounds reasonable quantities of drugs pursuant to or in anticipation of a valid prescription drug order;
 - (b) Distributes limited quantities of prescription drugs to practitioners or pharmacies for the purpose of alleviating temporary shortages or responding to emergencies;
 - (c) Distributes prescription drugs to practitioners or pharmacies for the purpose of supplying or replenishing reasonable quantities utilized by practitioners or pharmacies in the normal course of professional practice, if:
 1. A record of the transfer is maintained by both the transferring pharmacy and the receiving practitioner or pharmacy for a period of no less than five (5) years;
 2. The transfer is documented by purchase order or invoice and no prescription drug order shall be used to obtain supplies of drugs under this subsection;
 3. The total number of units transferred during a twelve (12) month period shall not exceed five percent (5%) of the total number of all units dispensed by the pharmacy during the immediate twelve (12) month period; and
 4. All distributions are in accordance with all applicable federal and state laws and administrative regulations; or
 - (d) Transfers prescription drug inventory from one pharmacy to another pharmacy to effect a permanent pharmacy closure.

Effective: July 15, 1996

History: Amended 1996 Ky. Acts ch. 257, sec. 6, effective July 15, 1996. -- Created 1982 Ky. Acts ch. 191, sec. 5, effective July 15, 1982.